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Food and Drug Administration

Center for Drug Evaluation and Research

Division of xxxxxxxxxxxxx

Central Document Room

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

**Re:** IND Exemption Determination for proposed protocol:

Study Title Here

Dear FDA Reviewer:

The purpose of this submission is to request a confirmation of my opinion that the proposed study of study drug name as a treatment for….. qualifies for **exemption from an IND** (21 CFR Part 312.2). The proposed clinical investigation is not being conducted to support a label-change of the product or to support a significant change in the marketing of the product.

Although the study drug is being used off-label from it’s FDA approved use, it has been shown to be safe and effective used at the proposed dose and route of administration in the study population. The rationale for this statement is provided below.

**Proposed Study:** We propose a multi-center, randomized, double-blinded, placebo-controlled trial to evaluate the effect of study drug versus placebo on proposed indictation

**Rationale for Safety of Proposed Study**

XXXX as an adjuvant to XXXXXX has been well studied and determined to be safe for patients with several studies of this topic coming out of UCLA. The most serious side effects include XXXXXXXXX These side effects are more common with XXXXXXX The injection itself can be painful and prospective subjects will be counseled on this point. Furthermore, in XXXXXXXXXXX

* **We are not seeking to report our findings to the FDA in support of a new indication for use. Nor is this study intended to support any other significant change in labeling of the drug.** study drug is currently FDA approved for use as an agent to treat xxxxxx. But like many medications, there are other uses for study drug for which there is no FDA approval. study drug is commonly used as a xxxxxx. study drug has long been used as a means of xxxxxxxx.
* study drug **is lawfully marketed and we do not seek to change advertising.**
* **The investigation does not involve a route of administration that significantly increases the risks associated with the use of the drug product.**

Describe route of administration

* **The investigation does not include a dosage level that significantly increases the risks associated with the use of the product.** The standard dosage is xxx for this indication. Data indicate that this dosage is safe for use.
* **The investigation does not involve use in a patient population that significantly increases the risks associated with the use of the drug product.**

The safety for patients and the efficacy in xxxxxx are both well established in the literature. This investigation does not propose to use study drug in any population that differs from when it has been used in the literature.

* **The investigation does not involve any other factor that significantly increases the risks associated with the use of the drug product.**
* **The investigation is conducted in compliance with the requirements for Institutional Review and the requirements for informed consent.**
* **The investigation is not promoting the drug being studied as safe and effective.** Safety for the patient and effectiveness in xxxxxx has been well established (as outlined in this rationale). This investigation is only seeking to determine whether administration of study drug versus placebo xxxxxxxxx.
* **This investigation does not provide for exemption for informed consent.** We will seek informed consent for all eligible subjects for this investigation.

References here

We respectfully ask that you review this request and inform us in writing if the IND requirement will be waived. If you require additional information, please contact me at the phone number or email address provided below. You may also contact xxxxxx at xxxxxxx who may act on my behalf.

Sincerely,

Name

Title

University of California, Los Angeles

Phone

email

Attachments:

Protocol

FDA form 1571

FDA form 1572